

**REMARKS**

Claims 1-5, 7-17, 25, 28, and 34-37 are pending in this application. Claims 35 and 36 are cancelled without prejudice. Applicants expressly reserve the right to pursue protection of any or all cancelled subject matter in a subsequent application.

Claims 2-4, 7, 9, 13, 17, 34 and 37 have been amended. Support for these claim amendments is discussed below. No new matter is introduced by these amendments and no new issues are raised. Entry of the amendments after final action is appropriate since the amendments are believed to place the claims in a condition for allowance.

**Upon entry of this amendment, claims 1-5, 7-17, 25, 28, 34, and 37 will be pending in this application.** Consideration of the pending claims is requested.

February 3, 2004 Telephone Conference with Examiner Belyavskyi

Applicants thank Examiner Belyavskyi for speaking with their representative, Debra A. Gordon, on the telephone on February 3, 2004. The Advisory Action was discussed. The Advisory Action states that the claim amendments set forth in the December 18, 2003 Response were not entered because claim 2, as amended therein, was allegedly incomplete for omitting an essential resolution step.

Applicants' representative explained that a resolution step was inadvertently omitted from amended claim 2 when each of the other limitations of claim 1 was incorporated into claim 2 (as discussed in detail below). Examiner Belyavskyi suggested that Applicants file this Second Amendment to incorporate the resolution step of claim 1 into claim 2. He agreed to enter the amended claims if the proposed claim 2 amendment eliminated the new issue raised by the Advisory Action, no other new issues were raised by this Second Amendment, and claims were in a condition for allowance.

Applicants have amended claim 2 herein as discussed with the Examiner.

November 25, 2003 Telephone Conferences with Examiner Belyavskyi

Applicants thank Examiner Belyavskyi for taking inquiry telephone calls from their representative, Debra A. Gordon, on November 25, 2003. Though the Examiner would not permit an after-final interview, he encouraged Applicants to submit an after-final amendment, which places claims that have not received a specific rejection into independent format.

Applicants asked the Examiner why the Rule 132 Declaration ("Declaration") submitted with the August 25, 2003 Response was not sufficient to overcome the §102(a) rejections of claims 1, 3, 4, 13-16. The Declaration stated that the non-inventor authors of the Dix *et al.* reference were not inventors and received knowledge of the invention from the inventors. The Examiner stated that only two of the four co-inventors listed on the present application are authors of the Dix *et al.* reference; thus, the Patent Office requires a statement explaining why the non-author co-inventors are not authors of the Dix *et al.* reference.

Information Disclosure Statement ("IDS")

Applicants thank the Examiner for reconsidering the references cited on the September 13, 2001 IDS, and for sending a copy of the Form 1449 acknowledging each of the references listed thereon.

Allowable Subject Matter

Independent claim 28, and its dependent claim 34, have not been rejected (or objected to) under any provision of U.S.C. Title 35. Thus, Applicants believe that such claims are allowable, and request their allowance.

Claim Rejections under 35 U.S.C. §112, 1st paragraph:

Claims 35 and 36 have been rejected under 35 U.S.C. §112, 1st paragraph (enablement requirement) because cell lines U251, A1207, and A1235 are allegedly not readily available to the public. Applicants respectfully disagree with this rejection for the reasons set forth in the August 25, 2003 Response. However to facilitate prosecution of the application, claims 35 and 36 have been cancelled. Thus, this rejection is moot, and Applicants request that it be withdrawn.

Claim Rejections under 35 U.S.C. §112, 2nd paragraph:

Claim 2 has been rejected under 35 U.S.C. §112, 2nd paragraph because allegedly there is insufficient antecedent basis for the phrase "... wherein incubation of monocytes, dendrites and B cells . . ." Applicants traverse this rejection at least because the allegedly indefinite phrase introduces a separable claim element and therefore does not require antecedent basis.

Only to facilitate prosecution of the application, claim 2 has been amended to recite that APCs comprise "macrophages, monocytes, dendritic cells, and/or B cells . . ." This amendment provides antecedent basis for the rejected claim language, as requested by the Examiner. This amendment is supported throughout the specification, for example, at page 2, lines 1-5, and at page 12, lines 20-29. In light of these amendments, Applicants request that this rejection be withdrawn.

Except for the above-discussed §112, ¶2 rejection, claim 2 has not been otherwise rejected. Thus, it is believed that claim 2 would be allowable if it were written in independent format incorporating all of the limitations of the claim(s) from which it depends. Accordingly, Applicants have further amended claim 2 to remove its dependency on claim 1 and to incorporate each of the limitations of claim 1.

As suggested by Examiner Belavskyi on February 3, 2004, Applicants have amended claim 2 to include the resolution step of claim 1. This resolution step recites, "... introducing a therapeutically effective amount of the APCs exposed to the immunosuppressive composition into a subject in whom a selectively inhibited immune response to the antigen is desired, wherein introduction of the APCs inhibits the immune response of the subject to the antigen." It is believed that this resolution step is acceptable to the Patent Office because such a step was added to claim 1 in apparent satisfaction of an earlier 35 U.S.C. §112, ¶2 rejection of claim 1 (see, Office action, dated March 25, 2003, and the August 25, 2003 Response thereto).

In light of the foregoing amendments and arguments, Applicants respectfully submit that amended claim 2 is in a condition for allowance. Moreover, claims 3-5, 7-17, 25, and 37 have

been amended to depend from now-independent amended claim 2. Thus, Applicants submit that each of such dependent claims is similarly allowable.

*Claim Rejections under 35 U.S.C. §102(a):*

Claims 1, 3, 4, and 13-16 have been rejected under 35 U.S.C. §102(a) as being allegedly anticipated by Dix et al., FASEB J., 13(4):A610, 1999 ("Dix"). Applicants traverse this rejection for the reasons set forth in the August 25, 2003 Response and for the further reasons set forth below.

As an initial matter, claims 3, 4 and 13-16 have been amended to depend (directly or indirectly) from amended claim 2, as discussed above. Claim 2 is not rejected under §102(a); thus, it is believed that this rejection is moot with regard to claims 3, 4 and 13-16, and Applicants request that it be withdrawn as to those claims.

As for claim 1, Applicants respectfully submit that the previously submitted Rule 132 Declaration has indeed overcome the §102(a) rejection. MPEP §2132.01 explains that a patent applicant can rebut a §102(a) rejection by submission of a declaration by the applicant establishing that the §102(a) reference describes the applicant's own work. The previously submitted Rule 132 Declaration established such facts, and should have been sufficient to overcome the §102(a) rejection.

Examiner Belyavskyi explained in a November 25, 2003 inquiry call to him, that the Patent Office requires a statement explaining why the non-author co-inventors are not authors of the Dix reference. The Dix reference is a one-paragraph abstract that, if it describes the invention at all, describes merely a small part of thereof. Thus, the non-author inventors are inventors of claimed subject matter not found in the Dix reference.

It appears that the Patent Office is requiring the Applicants to reaffirm the inventorship of the claimed subject matter. However, as stated in MPEP §2137.01, the "executors of [the] Oath or Declaration under 37 CFR 1.63 are presumed to be the inventors." The Office action has provided no evidence to suggest that the inventorship of the application is incorrect. Moreover,

inventorship of the claimed subject matter is completely separate from whether or not the claims are novel under 35 U.S.C. §102(a). Thus, Applicants request that the Examiner reconsider the Rule 132 Declaration submitted with the August 25, 2003 Response, and withdraw this rejection.

Regardless of the reconsideration of the Rule 132 Declaration requested above, Applicants also submit that Dix does not teach or suggest the characteristics of the one or more factors as recited in claim 1. Thus, Dix cannot anticipate (nor make obvious) claim 1. On this basis alone, this rejection should be withdrawn.

Additional Claim Amendments

Claim 28 has been amended to correct a grammatical error.

Claims 2 and 34 have been amended to refer to "dendritic cells" as such, rather than as "dendrites." This amendment is supported at least by original claim 13 and throughout the specification, for example, at page 12, lines 25-26.

**CONCLUSION**

It is respectfully submitted that the present claims are in a condition for allowance. If it may further issuance of these claims, the Examiner is invited to call the undersigned at the telephone number listed below.

Respectfully submitted,

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